R18 Consolidating guidelines for the prevention, detection and appraisal of reporting biases in clinical trials.

Publications

Dwan K, Altman DG, Clarke M, Gamble C, Higgins JPT, Sterne JAC, Williamson PR, Kirkham JJ. Evidence for the selective reporting of analyses and discrepancies in clinical trials: a systematic review of cohorts of clinical trials (*accepted PLoS Medicine*).

Dwan KM, Gamble C, Williamson PR, Kirkham JJ. Systematic Review of the Empirical Evidence of Study Publication Bias and Outcome Reporting Bias - an updated review. *PLoS ONE* 2013; **8**(7): e66844.

Presentations

- Review Congress in Chicago (2013) [http://www.peerreviewcongress.org/2013/Final-Program.pdf] [Oral presentation]

- Cochrane Colloquium in Quebec City (2013) [http://colloquium.cochrane.org/sites/colloquium.cochrane.org/files/uploads/content/CochraneQuebecBooklet_12-Sept-2013.pdf] [Poster presentation]

- 2nd UK Clinical Trials Methodology Conference, Edinburgh (2013) [http://www.methodologyconference2013.org.uk/wp-content/uploads/2013/09/CTMC-draft-programme-13.11-CURRENT.pdf] [Oral Presentation]

Impacts

Following a review of the empirical evidence (see above publications) and an international stakeholder meeting involving experts in selective reporting, there was much discussion about how selective reporting of analyses could be detected without access to trial statistical analysis plans (SAPS) (often a separate document to the trial protocol). There was also discussion around the lack of guidance on the contents of a SAP and at what point this should be made available. These discussions have led to a follow-up project entitled "*Development of Guidance for Statistical Analysis Plans for Clinical Trials*" which has also been funded by the HTMR network.

The New Cochrane Risk of Bias Tool that is currently being developed (set for initial launch end of 2014) has a number of domains, one of which is '*Bias in selection of reported result*', which covers both outcome reporting bias and analysis reporting bias. The writing of guidelines, handbook chapters and training materials will include reference and examples of selective reporting identified in this grant. The purpose of this is to help researchers identify and detect potential sources of selective reporting in both trial publications and non-randomised studies.

A long-standing successful workshop on outcome reporting bias in trials is to be updated to include the up-to-date empirical evidence of outcome reporting bias and to raise awareness of the types of selective reporting of analyses and the impacts (currently not included in the workshop). This updated workshop is to run amongst a group of researchers (including trialists) in Japan in November 2014.